UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/167,705	10/06/98	SCHMIDT A	55873JPWJML

HM12/0415

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EXAMINER	
HAMUD, F	
ART UNIT	**PAPER NUMBER**
1646	6

DATE MAILED: 04/15/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Offic Action Summary

Application No.	Applicant(s)
09/167,705	SCHMIDT et al
Examiner	**Group Art Unit**
Fozia Hamud	1646

☒ Responsive to communication(s) filed on *Mar 9, 1999*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *10-69* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *10-69* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

X Notice to comply with Sequence rules.

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

Applicants are advised that claims 32 and 51 are improper Markush claims because the multiple elements recited therein are peptides, inorganic chemicals and nucleic acids which do not share a common technical feature which is based on a common property or special technical feature not found in the prior art. These peptides, inorganic chemicals and nucleic acids are independent and distinct chemical compounds lacking either a common structural property which distinguishes them as group from structurally related compounds of the prior art or which provides them with a common utility which is lacking from those prior art peptides, inorganic chemicals and nucleic acids.

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 10-14, drawn to a host cell with a vector comprising an isolated nucleic acid molecule encoding EN-RAGE peptide, classified in class 536, subclass 23.5.

Group II. Claims 15-16, drawn to a pharmaceutical composition comprising an EN-RAGE peptide, classified in class 514, sub class 2.

Group III. Claim 17, drawn to an antibody which specifically binds with EN-RAGE peptide, classified in class 530, sub class 387.1.

Group IV. Claim 18, drawn to a ribozyme which is capable of specifically cleaving EN-RAGE mRNA in a cell, classified in class 536, sub class 23.2.

Group V. Claims 19-25, drawn to a transgenic nonhuman mammal whose germ or somatic cells contains a nucleic acid molecule which encodes EN-RAGE peptide introduced into the mammal or an ancestor at an embryonic stage, classified in class 800, sub class 21.

Group VI. Claims 26-43, 69, drawn to a method for determining whether a compound is capable of inhibiting the interaction between EN-RAGE peptide and a RAGE peptide, classified in class 435, subclass 7.21.

Group VII. Claims 44-46, drawn to a composition that inhibits the interaction of EN-RAGE useful for the suppression of inflammation in a subject, class and sub class undeterminable.

Group VIII. Claims 47-48, 50-52, 54-68, drawn to a method of inhibiting inflammation in a subject which comprises administering to the subject an anti-EN-RAGE antibody capable of interfering with the interaction between EN-RAGE peptide and its receptor, classified in class 424, sub class 139.1.

Group IX. Claims 47, 49-51, 54-68, drawn to a method for inhibiting inflammation in a subject which comprises administering to the subject a peptide capable of interfering with the interaction between EN-RAGE peptide and its receptor, classified in class 514, sub class 2.

Group X. Claims 47, 50-51, 53-68, drawn to a method for inhibiting inflammation in a subject which comprises administering to the subject a nucleic acid molecule capable of interfering with the interaction between EN-RAGE peptide and its receptor, classified in class 514, sub class 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III, IV, V and VII are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention which cannot be exchanged. The nucleic acid of Group I can be used to make a hybridization probe or can be used in gene therapy as well as in the production of EN-RAGE protein. The pharmaceutical composition of Group II can be used other

than to make the antibody of Group III, such as used as a probe, or used therapeutically or diagnostically (e.g. in screening). Although the antibody of Group III can be used to obtain the nucleic acid of Group I, it can also be used in diagnostics (e.g. as a probe in immunoassays, or in immunochromatography) or it may be used therapeutically. The ribozyme of Group IV can be used to inhibit the expression of mRNA, and the transgenic nonhuman mammal of Group V can be used to produce large quantities of the protein of interest, however, they are structurally and functionally different each from the other and each from Groups I-III. A search from any of the above Groups would not necessarily reveal art to any other Group.

Inventions I, II and VI, VIII-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acid of Group I and the pharmaceutical composition of Group II, are neither used nor produced in the methods of Groups VI, VIII-X.

Inventions III and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the antibody of Group III as claimed can also be used in diagnostics (e.g. as a probe in immunoassays, or in immunochromatography).

Inventions III and VI, IX-X unrelated to inventions. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of

operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the antibody of Group III, is neither used nor produced in the methods of Groups VI, IX-X.

Inventions IV, V, VII are unrelated to inventions VI, VIII-X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case, the ribozyme of Group IV, the transgenic nonhuman mammal of Group V and the composition of Group VII are neither used nor produced in the methods of Groups VI, VIII-X.

Inventions VI, VIII-X are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has prima facie shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

2. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is given ONE MONTH, or THIRTY DAYS, whichever is longer, from the mailing date of this letter within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8896. The examiner can normally be reached on Monday-Friday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2731.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Art Unit: 1646

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud FH
Patent Examiner
Group1646
April 12, 1999

Prema Mertz
PREMA MERTZ
PRIMARY EXAMINER

paper # 6 Application No. 09/167,705

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 CFR 1.8 1.825. Applicant's attention is directed to these regulations, published at 114 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitte However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of marked-up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has bee found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as requi by 37 CFR 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e).

☐ 7. Other: _____

Applicant must provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing"

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification

☒ A statement that the content of the paper and computer readable copies are the s and, where applicable, include no new matter, as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d)

For questions regarding compliance with these requirements, please conta

For Rules Interpretation, call (703) 308-1123
For CRF submission help, call (703) 308-4212
For PatentIn software help, call (703) 557-0400

Please return a copy of this notice with your response.